

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listing, of claims in the application.

Listing of Claims

Claims 1-17. (Canceled)

18. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:
- providing a member having a plurality of stratum corneum-piercing microprotrusions;
 - applying an aqueous solution of the pharmacologically active agent onto the member; and
 - drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;
- wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;
- and
- wherein the method provides uniformity of coating from microprotrusion to microprotrusion.
19. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:
- providing a member having a plurality of stratum corneum-piercing microprotrusions;
 - applying an aqueous solution of the pharmacologically active agent onto said microprotrusions; and
 - drying said applied aqueous solution to form a dry agent-containing coating on said microprotrusions, said coating being less than a thickness of the microprotrusions;
- wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

20. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions; said microprotrusions adapted to pierce through the stratum corneum to a depth of less than about 500 micrometers;

applying an aqueous solution of the pharmacologically active agent onto the member; and drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

21. (Canceled).

22. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions, said microprotrusions having a length of less than 500 micrometers and a thickness of less than 25 micrometers;

applying an aqueous solution of the pharmacologically active agent onto the member; and drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

23. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member; said pharmacologically active agent selected from the group consisting of adrenocorticotrophic hormone (ACTH (1-24)), calcitonin, desmopressin, leutinizing hormone releasing hormone (LHRH), goserelin, leuprolide, buserelin, triptorelin, parathyroid hormone (PTH), vasopressin, deamino [Val4, D-Arg8] arginine vasopressin, interferon alpha, interferon beta, interferon gamma, follicle stimulating hormone (FSH), erythropoietin (EPO), granulocyte macrophage colony stimulating factor (GM-CSF), granulocyte colony stimulating factor (G-CSF), interleukin-10 (IL-10), glucagon, and growth regulatory factor (GRF); and

drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;
wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

24. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent desmopressin onto the member; and
drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

25-27. (Canceled)

28. (Canceled)

29. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratus corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said

member, said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

30. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said

member, said coating being less than a thickness of the microprotrusions;

wherein said agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of

greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 50 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

31. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member; and
drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating having a thickness over a surface of said member of less than 50 micrometers;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

32. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member; and
drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating having a thickness over a surface of said member of less than 25 micrometers;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

33. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

- providing a member having a plurality of stratum corneum-piercing microprotrusions;
- providing an aqueous solution comprising said pharmacologically active agent and an adjuvant;

- applying said aqueous solution onto the member; and

- drying said applied aqueous solution to form a dry agent-containing and adjuvant-containing coating on said member, said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

34. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

- providing a member having a plurality of stratum corneum-piercing microprotrusions;

- applying an aqueous solution of the pharmacologically active agent onto the member; and

- drying said applied aqueous solution to form a dry agent-containing coating on said

- member; said coating comprising a loading of said pharmacologically active agent of less than 1 mg/cm² of area of said member, and said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

35. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member; and
drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating comprising a loading of said pharmacologically active agent of less than 0.5 mg/cm^2 of area of said member, and said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said agent having an aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

36-46 (Cancelled).

47. (Previously presented) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto said member by dip coating said member in said solution; and
drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C of less than about 500 centipoises;

and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

48-50. (Canceled)

51. (Cancelled)

52. (Currently amended) The method of claim 19 [[51]], wherein the coating provides systemic delivery of about 25% to 50% of the agent upon application of the device to the skin of a subject for 5 seconds and wherein the agent comprises desmopressin or hGH.

53. (Cancelled)